

REMARKS

Claims 1-51 and 53-69 are pending. Of these, claims 8-10, 27-31, 39, 41-45, 55-59, 68 and 69 have been withdrawn from consideration. Claims 52 and 70 are canceled. Reconsideration of the application in view of the current claims is respectfully requested and further in view of the following remarks.

I. CLAIM REJECTIONS UNDER 35 U.S.C. § 102

A. The Examiner has rejected claims 1-7, 11-15, 33-36, 38, 40, 46, 53, 54 and 57 under 35 U.S.C. § 102(b) as being anticipated by Mazzocchi US Patent No. 6,506,204 (hereinafter "Mazzocchi"). Applicant respectfully traverses the above rejection as Mazzocchi does not disclose every limitation of the claimed invention.

According to the MPEP 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." The Examiner asserts that "Mazzocchi discloses an implant comprising an inflatable partitioning element (60) having an outer periphery with a proximal face (70), at least one anchoring element (72), and a hub (15)." See Final Office Action, page 3. The Examiner further "has interpreted the word "inflatable" as "something that expand[s] or increase[s] abnormally." See Final Office Action, page 4. The Examiner did not cite a source for that definition other than to say that it was "disclosed in the M-W dictionary."

"Inflatable" as used in the specification of the application refers to "[t]he inflatable partitioning and support elements [which] may be inflated with a variety of fluids, preferably liquids such as saline or contrast fluids." See para 0033, lines 1-3. Inflate as used in this sense conforms to definition 1 in the Shorter Oxford Dictionary of "distend by filling with air or gas: *gen.* swell, distend." See Shorter Oxford Dictionary, page 1370, 2002. The Examiner's definition of "inflatable" as something that expands or increases abnormally is not used in the Shorter Oxford Dictionary as pertaining to an object, but is confined to economic terms: "[i]ncrease greatly or beyond accepted limits; *spec.* (ECONOMICS) bring about inflation in relation to (currency, an economy), raise (prices) artificially." See Shorter Oxford Dictionary, page 1370, 2002. Therefore, it does not comport with the sense of "inflatable" as is used in the specification of the application.

Independent claims 1, 33, 53, and 67 all recite a device for treating a patient's heart comprising "an inflatable partitioning element" or "an inflatable partitioning means". Mazzocchi does not disclose an "inflatable partitioning element" or "inflatable partitioning means". Mazzocchi discloses an aneurysm occlusion device formed from a "resilient metal fabric". See Mazzocchi, col. 3, lines 23-25. This device is not inflatable; it is "deformed" by heat to conform to a molding surface to set the fabric in its deformed state." See Mazzocchi, col. 3, lines 30-35. The devices of Mazzocchi have only two configurations, an expanded configuration and a collapsed configuration. See Mazzocchi, col. 3, lines 59-61. "The devices are collapsed for deployment through a catheter and, upon exiting the distal end of the catheter in a patient's channel, will resiliently substantially return to their expanded configuration." See Mazzocchi, col. 3, lines 61-65. Therefore, as soon as the device of Mazzocchi exits the catheter, it expands to its only other configuration.

Therefore, Mazzocchi does not disclose an inflatable partitioning element or inflatable partitioning means as those terms are used in Applicants' specification and claims.

Additionally, claims 1 and 33 recite the limitation of a device which has an outer periphery that is configured to engage the heart and be secured within the heart "to partition a [ventricular] chamber of the patient's heart into a main productive and a secondary, non-productive portion." The Examiner has declined to give weight to this limitation on the grounds that it is functional. Claim 1, however, recites structure—the element's outer periphery—as well as details about that element's structural configuration in a manner that describes what the element is, not merely what it does. In this way, claim 1 is very different from the claims at issue in the cases cited by the Examiner, notwithstanding the broad statements the Examiner quoted from those cases out of context from their facts.

Likewise, claim 53 recites details about an inflatable partitioning element—a definite part of the device's structure—in terms of its configuration to partition a ventricular chamber. Further, claim 53 recites the limitation of "an interior configured to receive inflation fluid," another definite structural limitation. Finally, claim 67 recites an inflatable element (i.e., structure) in terms of its configuration to partition a ventricular chamber. Claims 53 and 67 each recite their structure in a manner that describes what the element is, not merely what it does. There is no support in the

patent statute or in the case law for ignoring these positive structural limitations in an apparatus claim.

Mazzocchi discloses a device that occludes an aneurysm in a lumen. It cannot be a partition in the ventricle as there is no way to secure the device within the ventricular chamber to partition the chamber. The device of Mazzocchi requires insertion into an aneurysm, using the constricted neck to hold the device in place.

When the anchor 70 is deployed in the lumen of the vessel V after deploying the body portion 80 in the aneurysm A, the central portion 62 of the occluder will tend to be automatically positioned in the neck N of the aneurysm . . . As the body portion is larger than the neck N and will resist pulling out of the aneurysm, the occluder will be firmly seated in the aneurysm.

See Mazzocchi, col. 16, lines 55-63. The device of Mazzocchi requires lodging against the folded over tissue of the neck of an aneurysm. Nowhere does Mazzocchi disclose a device which can be structurally secured as a partition in a ventricle of the heart or could withstand the pressure of the heart cycle. Mazzocchi is silent on how to partition the ventricle of a heart. In addition, Mazzocchi does not disclose a device having an interior configured to receive inflation fluid.

Mazzocchi therefore does not anticipate apparatus claims 1, 21, 33, 53 or 67.

Based on the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 1-7, 11-15, 33-36, 38, 40, 46, 53, 54 and 57 under 35 U.S.C. § 102(b) as being anticipated by Mazzocchi .

B. The Examiner has rejected claims 1-3, 5-7, 15-26, 32, 53, 54, 60 and 61 under 35 U.S.C. § 102(e) as being anticipated by Van Tassel et al. U.S. Patent No. 6,652,555 (hereinafter "Van Tassel").

Applicant respectfully traverses the rejection as Van Tassel does not disclose every limitation of the present claims.

Independent claim 1 recites the limitation of an "inflatable partitioning element which has an outer periphery configured to engage surfaces of a ventricular chamber of the patient's heart to partition the chamber into a main productive and a secondary, non-productive portion." Van Tassel, on the other hand, places a balloon into an atrial appendage. Van Tassel is silent on how to

partition the much larger volume of the ventricle and how to retain the partition in place against the pressure of the heart cycle. The anchor elements of Van Tassel require pressing against the constricted neck (ostium) of the atrial appendage, or bracing against or pinching tissue outside of the ventricle (i.e. the atrial appendage). See Van Tassel, Figure 18. A device configured to fit within an atrial appendage is not configured to partition a ventricle.

In addition, claim 1 recites an anchoring element configured to secure the inflatable element within the ventricle. Van Tassel discloses no such element. Van Tassel therefore does not anticipate claim 1.

Claim 21 recites a device with an inflatable partitioning element configured to partition a ventricular chamber into productive and non-productive portions. Once again, Van Tassel's device is configured to fit within an atrial appendage and is not configured to partition a ventricle.

In addition, claim 21 recites a distally extending supporting element configured to engage a region of the non-productive portion of the ventricular chamber. Van Tassel has no such element. Van Tassel therefore does not anticipate claim 21.

Claim 53 recites a device with an inflatable partitioning means configured to partition a ventricular chamber into productive and non-productive portions. Once again, Van Tassel's device is configured to fit within an atrial appendage and is not configured to partition a ventricle.

In addition, claim 53 recites a distally extending supporting means configured to engage a region of the non-productive portion of the ventricular chamber. Van Tassel has no such element. Van Tassel therefore does not anticipate claim 53.

Based on the foregoing, Applicant respectfully requests withdrawal of the rejection of claims 1-3, 5-7, 15-26, 32, 53, 54, 60 and 61 over Van Tassel under 35 U.S.C. § 102(b).

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(A)

The Examiner has rejected Claims 21 and 37 under 35 U.S.C. § 103(a) as being unpatentable over Mazzocchi in view of Lichtenstein U.S. Patent Pub. 2005/0015109 (hereinafter Lichtenstein).

According to the MPEP 2143, a *prima facie* case of obviousness can be established only if three criteria have been met. "First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to

modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.”

Applicant respectfully requests withdrawal of the rejection because a *prima facie* case of obviousness cannot be established against the claims.

For example, claims 21 and 33 recite a device with the limitations of “an inflatable partitioning element” or “an inflatable partitioning means.” See claim 21 and 33. Claim 37 recites the limitations of the device according to Claim 36 wherein the anchoring means comprise a hook or a barb. Since Claim 37 depends on Claims 33 and 36, all of the claim limitations of Claim 33 and 36 are incorporated in Claim 37. As discussed above, Mazzocchi does not teach or suggest an inflatable partitioning element. Mazzocchi teaches a device which is deformed under heat and has two configurations, collapsed and expanded. Nowhere does Mazzocchi teach or suggest an inflatable partitioning device.

Lichtenstein does not cure the defect of Mazzocchi. Lichtenstein teaches “devices and methods of altering blood flow in the left ventricle.” See Lichtenstein, page 1, para 0003. The devices of Lichtenstein “are movable between collapsed and expanded conditions.” See Lichtenstein page 1, para 0003. Nowhere does Lichtenstein teach or suggest an inflatable partitioning element. Therefore, Mazzocchi and Lichtenstein (independently or in combination) do not teach or suggest all the limitations of independent claims 21 and 44. Further, there is no teaching or suggestion in Lichtenstein to modify the device of Mazzocchi to arrive at the presently claimed invention. Even if the inventions of Mazzocchi and Lichtenstein were somehow to be combined, one would not arrive at the present invention. Therefore a *prima facie* case of obviousness can not be established against claims 21 and 33. As claim 37 is dependent on claim 33, it incorporates all the limitations of claim 33, and a *prima facie* case of obviousness cannot be established against it. Therefore, the above rejection cannot stand. Based on the foregoing, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. 103(a) of Claims 21 and 37.

III. THE OMITTED CLAIMS

The Examiner's rejection failed to address pending claims 47-51 and 62-66. In the absence of a rejection, these claims should have been indicated as having been allowed.

CONCLUSION

For the foregoing reasons, Applicant requests the Examiner allow claims 1-7, 11-26, 32-38, 40, 46-51, 53, 54, and 60-67 and advance the application to issuance.

FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **23-2415** (Docket No. 33108-703.201).

Respectfully submitted,

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By:

Peggy Radeff
Peggy Radeff
Registration No. 57,258

WILSON SONSINI GOODRICH & ROSATI
650 Page Mill Road
Palo Alto, CA 94304-1050
Direct Dial: (650) 565-3610
Customer No. 21971